



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0235; FRL-9950-04]

Chlorantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of chlorantraniliprole in or on multiple commodities which are identified and discussed later in this document.

Interregional Research Project Number 4 (IR-4) requested the tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0235, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202)

566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0235 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0235, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 22, 2016 (81 FR 40594) (FRL- 9947-32), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP# 6E8477) by IR-4, 500 College Road East, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)-carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on the raw agricultural commodities teff, forage at 40 parts per million (ppm); teff, grain at 6.0 ppm; teff, hay at 40 ppm; teff, straw at 40 ppm; quinoa, forage at 40 ppm; quinoa, grain at 6.0 ppm; quinoa, hay at 40 ppm; and quinoa, straw at 40 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by DuPont Crop Protection, the registrant, which is available in the docket EPA-HQ-OPP-2013-0235 at <http://www.regulations.gov>.

A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the

tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for chlorantraniliprole in or on teff forage, grain, hay and straw as well as quinoa forage, grain, hay and straw, consistent with FFDCA section 408(b)(2).

In the **Federal Register** of February 7, 2014 (79 FR 7397) (FRL-9905-56), EPA established tolerances for residues of chlorantraniliprole in or on fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; onion, green subgroup 3-07B at 3.0 ppm; peanut, hay at 90 ppm; and peanut at 0.06 ppm. EPA is relying upon the risk assessments that supported the findings made in the February 7, 2014 **Federal Register** document in support of this action. The toxicity profile of chlorantraniliprole has not changed, and the previous risk assessments that supported the establishment of those tolerances remain valid.

The Agency evaluated the request to establish tolerances in or on quinoa and teff forage, grain, hay, and straw and concluded that the aggregate exposure and risks would not increase as a result of the proposed use on quinoa and teff and are the same as those estimated in the February 7, 2014 final rule.

Both quinoa and teff are prepared like other whole grains, such as rice and barley, and may also be used to make flour in a manner similar to wheat and other cereal grains. Therefore, EPA concludes that teff and quinoa will likely substitute in the diet for cereal grain foods, which are subject to tolerances for chlorantraniliprole, and would be assumed to contain similar residues. Additionally, since teff and quinoa use patterns are similar to those for wheat and barley, increased exposures to individuals through drinking water is not expected. Thus, the proposed teff and quinoa uses will not result in higher dietary exposure estimates.

With respect to livestock commodities, residues of chlorantraniliprole in teff and quinoa livestock feeds are expected to be similar to those in other forages, hays, and silages for which chlorantraniliprole is currently registered. Therefore, there would be no increase in the livestock dietary burden should teff and quinoa be substituted in the livestock diet for other hays and silages; residues in meat, milk, poultry and eggs will remain the same.

EPA concludes that the aggregate exposure and risk estimates presented in the most recent human health risk assessment document, which were not of concern to the Agency, adequately account for exposures and risk resulting from all chlorantraniliprole uses including the proposed teff and quinoa uses.

Therefore, EPA relies upon the findings made in the February 7, 2014 **Federal Register** document in support of this rule. EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorantraniliprole residues.

For a detailed discussion of the aggregate risk assessments and determination of safety for these tolerances, please refer to the February 7, 2014 **Federal Register** document and its supporting documents, available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2013-0235. Further information about EPA's determination that an updated risk assessment was not necessary may be found in the document, "Chlorantraniliprole: Aggregate Human Health Risk Assessment for the Proposed New Uses on Teff and Quinoa" in docket ID number EPA-HQ-OPP-2013-0235.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, liquid chromatography mass spectrometry/mass spectrometry (LC/MS/MS); Method DuPont-11374, is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs for chlorantraniliprole residues in or on quinoa or teff.

C. Response to Comments

EPA received one comment to the Notice of Filing that stated, in part, that this chemical is “dangerous to America and to health of our people and life in America” and that EPA should “deny those applications from the profiteers whose only aim is to make money at our expense.” The Agency understands the commenter’s concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen’s comment appears to be directed at the underlying statute and not EPA’s implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

V. Conclusion

Therefore, tolerances are established for residues of chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)-carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on quinoa, forage at 40 ppm; quinoa, grain at 6.0 ppm; quinoa, hay at 40 ppm; and quinoa, straw at 40 ppm; teff, forage at 40 ppm; teff, grain at 6.0 ppm; teff, hay at 40 ppm; and teff, straw at 40 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 26, 2016.

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.628, add alphabetically the entries “Quinoa, forage”, “Quinoa, grain”, “Quinoa, hay”, “Quinoa, straw”, “Teff, forage”, “Teff, grain”, “Teff, hay”, and “Teff, straw” to the table in paragraph (a) to read as follows:

§ 180.628 Chlorantraniliprole; pesticide tolerances.

(a) * * *

Commodity	Parts per million

Quinoa, forage	40
Quinoa, grain	6.0
Quinoa, hay	40
Quinoa, straw	40

Teff, forage	40
Teff, grain	6.0
Teff, hay	40
Teff, straw	40

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